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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/567,051	01/29/2007	Chris Cindrich	P-6244/C	4876

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EXAMINER	
SCHMIDT, EMILY LOUISE	

ART UNIT	PAPER NUMBER
3767	

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12/02/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/567,051	CINDRICH ET AL.	
	Examiner	Art Unit	
	Emily Schmidt	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 September 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lavi et al. (US 2002/0055711 A1) in view of Hart (US 5,976,111).

With regard to claims 1 and 6, Lavi et al. teach a device for delivering a medicament into a body of a patient by injection into or through a skin surface of said patient, comprising: a housing having a bottom surface adapted to contact a skin surface of a patient, and a top surface (Fig. 17 bottom surface 210, top surface generally indicated at 220); an injection needle adapted for penetration of said skin surface and for movement through a needle aperture (Fig. 17 needle N); a reservoir (connects at 273 Fig. 20a, [0083] ports connect to reservoirs not shown), said reservoir in fluid communication with said injection needle (Fig. 20a communication through 274); and a safety member adapted for movement away from said bottom surface of said housing (Fig. 17 member 231), said safety member having a covering portion disposed about said needle aperture (Fig. 17 member 235), and at least one shield protruding from said covering portion (Fig. 17 walls of 231 extending up from 235), said safety member having a first position wherein said shield of said safety member is initially disposed within said housing and said covering portion is substantially co-planar with said bottom surface of said housing (Fig. 17), and a second position wherein said shield of said safety member is at least partially withdrawn from said housing and at least partially covers said injection needle (Fig. 20); a spring element

configured to bias said shield and covering portion of said safety member toward said second position (Fig. 20 spring 232, [0133]); and a rotatable door disposed upon said bottom surface of said housing and having a first position, which prevents movement of said safety member, and a second position, which allows movement of said safety member (Fig. 17 members 237, [0127], member 237 is disposed on the bottom surface on its surface opposite the surface which contacts the body via the portion connected with 284); wherein when said device is placed upon said skin surface of said patient and activated, said rotatable door is released and free to rotate from said first position to said second position and said spring element is free to urge said safety member into said second position, whereby, as said device is removed from said skin surface, said shield of said safety member emerges from said housing and at least partially covers said injection needle (see transition form Fig. 17-Fig. 20, [0127]). As the reservoir is not shown, Lavi et al. do not explicitly disclose a reservoir within the housing. However, Hart shows a needle protection device which is equivalently attached to a syringe reservoir or catheter to provide fluid to the needle (Figs. 3 and 4 syringe 10, Col. 3 lines 26-31). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to connect the device of Lavi et al. to a syringe as Hart teaches such is an art recognized equivalent for supplying fluid to a needle protection system and Lavi et al. teach the device is connected to a reservoir. The reservoir would be considered as part of the housing and would be disposed within the housing as connected to the needle mechanism. Such a syringe would also comprise a plunger pressurization system.

With regard to claims 2 and 5, Lavi et al. teach a device for delivering a medicament into a body of a patient by injection into or through a skin surface of said patient, comprising: a housing having a bottom surface adapted to contact a skin surface of a patient, and a top surface (Fig. 17 bottom surface 210, top surface generally indicated at 220); an injection needle adapted for penetration of said skin surface and for movement through a needle aperture (Fig. 17 needle N); a reservoir, said reservoir in fluid communication with said injection needle (connects at 273 Fig. 20a, [0083] ports connect to reservoirs not shown, in connection through 274); and a safety member adapted for linear movement substantially perpendicular to said bottom surface of said housing (Fig. 17 member 231), said safety member having a skin contacting portion disposed about said needle aperture (Fig. 7 member 235), and at least one shield protruding from said skin contacting portion (Fig. 17 walls of 231 extending up from 235) and configured to be held in place by a device activation button (Fig. 17 member 260), said safety member having a first position wherein said shield of said safety member is initially disposed within said housing and held in place by said device activation button, and said skin contacting portion is substantially co-planar with said bottom surface of said housing, and a second position wherein said shield of said safety member is released by activation of said device activation button and is at least partially withdrawn from said housing substantially perpendicular to said bottom surface, and at least partially covers said injection needle (see transition from Fig. 17 to Fig. 20, [0127], [0133]). As the reservoir is not shown, Lavi et al. do not explicitly disclose a reservoir within the housing. However, Hart shows a needle protection device which is equivalently attached to a syringe reservoir or catheter to provide fluid to the needle (Figs. 3 and 4 syringe 10, Col. 3 lines 26-31). It would have been obvious to a person of ordinary skill in the art at the time the invention was

made to connect the device of Lavi et al. to a syringe as Hart teaches such is an art recognized equivalent for supplying fluid to a needle protection system and Lavi et al. teach the device is connected to a reservoir. The reservoir would be considered as part of the housing and would be disposed within the housing as connected to the needle mechanism. Such a syringe would also comprise a plunger pressurization system. The embodiment of Lavi et al. in Figs. 17-20 does not teach an adhesive on the skin contacting surface. However, Lavi et al. teach in the embodiments of at least Figs. 1-16 that the device is adhesively attached to the skin (Fig. 3 adhesive 17). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to adhesively attach portion 235 to the skin in the embodiment of Figs. 17-20 as in at least Figs. 1-16 since it has been held that combining two embodiments disclosed adjacent to each other in a prior art patent does not require a leap of inventiveness and involves only routine skill in the art, Boston Scientific v. Cordis Fed. Cir. 2009. Such attachment would function that then the device is removed from the skin surface the adhesion would aid in moving the safety member between positions.

With regard to claims 3 and 4, Lavi et al. teach a device for delivering a medicament into a body of a patient by injection into or through a skin surface of a patient, comprising: a housing having a bottom surface, and a top surface (Fig. 17 bottom surface 210, top surface generally indicated at 220); an injection needle adapted for penetration of said skin surface and for movement through a needle aperture (Fig. 17 needle N); and a safety member (Fig. 17 member 231 with 237) adapted for rotational movement along an arcuate path relative to said bottom surface of said housing (Figs. 17-20 see transition of 237), said safety member having a skin contacting portion disposed about said needle aperture (Fig. 19), and a pivot (Figs. 17-20 see

pivot point of member 237), said safety member having a first position wherein said safety member is secured against said bottom surface and substantially co-planar with said the bottom surface of said housing (Fig. 19), and a second position wherein said safety member is released and rotated about said pivot and said safety member at least partially covers said injection needle (Fig. 20); wherein when said device is placed upon said skin surface of said patient and activated, said securing means is released by activation of said device and said skin contacting portion of said safety member ([0127], [0131]). As the reservoir is not shown, Lavi et al. do not explicitly disclose a reservoir within the housing. However, Hart shows a needle protection device which is equivalently attached to a syringe reservoir or catheter to provide fluid to the needle (Figs. 3 and 4 syringe 10, Col. 3 lines 26-31). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to connect the device of Lavi et al. to a syringe as Hart teaches such is an art recognized equivalent for supplying fluid to a needle protection system and Lavi et al. teach the device is connected to a reservoir. The reservoir would be considered as part of the housing and would be disposed within the housing as connected to the needle mechanism. Such a syringe would also comprise a plunger pressurization system. The embodiment of Lavi et al. in Figs. 17-20 does not teach an adhesive on the skin contacting surface. However, Lavi et al. teach in the embodiments of at least Figs. 1-16 that the device is adhesively attached to the skin (Fig. 3 adhesive 17). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to adhesively attach portion 235 to the skin in the embodiment of Figs. 17-20 as in at least Figs. 1-16 since it has been held that combining two embodiments disclosed adjacent to each other in a prior art patent does not require a leap of inventiveness and involves only routine skill in the art, Boston

Scientific v. Cordis Fed. Cir. 2009. Such attachment would function that then the device is removed from the skin surface the adhesion would aid in moving the safety member between positions.

3. Claims 3 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gross et al. (US 6,500,150 B1) in view of Gross et al. (US 5,997,501).

With regard to claim 3, Gross et al. '150 teach a device for delivering a medicament into a body of a patient by injection into or through a skin surface of a patient, comprising: a housing having a bottom surface, and a top surface (Fig. 11 device 10); an injection needle adapted for penetration of said skin surface and for movement through a needle aperture (Fig. 11 needle 17); a reservoir, disposed within said housing, said reservoir in fluid communication with said injection needle (Fig. 1 barrel 12); and a safety member (Fig. 11 member 22) adapted for rotational movement along an arcuate path relative to said bottom surface of said housing, said safety member having a skin contacting portion disposed about said needle aperture and is substantially covered with adhesive (Col. 8 lines 5-6), and a pivot (Fig. 1 about hinge 23), said safety member having a first position wherein said safety member is secured against said bottom surface and substantially co-planar with said the bottom surface of said housing (Fig. 12), and a second position wherein said safety member is released and rotated about said pivot and said safety member at least partially covers said injection needle (Fig. 13); wherein when said device is placed upon said skin surface of said patient and activated, said skin contacting portion of said safety member is temporarily adhered to skin surface and when said device is removed from said skin surface, said adhesion of said safety member to said skin surface is sufficient to rotate said

safety member about said pivot from said first position to said second position (Col. 10 lines 14-22). Gross et al. '150 do not disclose a securing means which secures the safety member against the bottom surface and which when released by activation of said device allows the safety member to move to the second position. However, Gross et al. '501 teach a drug delivery device which uses protuberances in detents to hold the device with the needle in the extended and retracted positions (Figs. 15 and 16, members 306 and 305, Col. 15 lines 7-12). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use the protuberance and detent system of Gross et al. '501 in Gross et al. '150 such that the end of 22 which extends past the needle on the end opposite the hinge as a protuberance which would fit in a detent on member 11 when the needle is in the extended position to hold the needle in position as in Gross et al. '501 because this would increase device safety by preventing needle movement unless initiated by the user. To use the device the user must activate the device to move the needle.

With regard to claim 4, see Col. 8 lines 34-41.

Response to Amendment

4. The amendments to the claims have been entered.

Response to Arguments

5. Applicant's arguments filed September 27, 2010 have been fully considered but they are not persuasive. Regarding Applicant's arguments with respect to Lavi and Hart, the Examiner maintains that the syringe body would be included as part of the device and as such the reservoir

is within the housing. Regarding Applicant's arguments with respect to the door of claim 1, the claim does not recite that the rotatable door is configured to contact the skin. The Examiner finds the indicated door of Lavi to be disposed upon the bottom surface of the housing which contacts the skin as indicated above. The claim does not provide any further recitation as to the orientation of the door with respect to the bottom surface. Regarding Applicant's arguments with respect to Gross, the claims do not recite any limitations as to what constitutes device activation, the Examiner finds that when the user is manipulating the device they are activating the device. When the user moves the device of Gross between extended and retracted positions they are activating the device, the device can not be used or activated unless the needle is moved into position to penetrate the skin. In view of the amendments claims 3 and 4 have also been rejected over Lavi and Hart.

Conclusion

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Schmidt whose telephone number is (571) 270-3648. The examiner can normally be reached on Monday through Thursday 7:30 AM to 5:00 PM (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Emily Schmidt/
Examiner, Art Unit 3767

/KEVIN C. SIRMONS/

Supervisory Patent Examiner, Art Unit 3767